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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,868	10/15/2001	Frank B. Dean	13172.0012U1	3745

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EXAMINER	
HORLICK, KENNETH R	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/977,868	DEAN ET AL.	
	Examiner	Art Unit	
	Kenneth R Horlick	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-296* is/are pending in the application.

4a) Of the above claim(s) *162-213 and 288-296* is/are withdrawn from consideration.

5)☒ Claim(s) *137,143-160 and 214-287* is/are allowed.

6)☒ Claim(s) *1-10,27,36,111-136,138,139 and 161* is/are rejected.

7)☒ Claim(s) *11-26,28-35,37-110 and 140-142* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/3/04;6/13/03;9/3/02; 3/26/02* (7 pages)
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-161 and 214-287, drawn to methods of amplifying a target nucleic acid via strand displacement replication, classified in class 435, subclass 91.2.

II. Claims 162-169, drawn to a method of labeling nucleic acids, classified in class 435, subclass 91.1.

III. Claim 170, drawn to a microarray, classified in class 536, subclass 24.3.

IV. Claims 171-182, drawn to a method of generating probes for hybridization, classified in class 435, subclass 6.

V. Claims 183-210, drawn to a method of amplifying messenger RNA, classified in class 435, subclass 91.2.

VI. Claim 211, drawn to a method of amplifying a target nucleic acid using partially degraded RNA, classified in class 435, subclass 91.2.

VII. Claims 212-213, drawn to a method of comparative genome hybridization, classified in class 435, subclass 6.

VIII. Claims 288-296, drawn to kits, classified in class 435, subclass 91.2.

The inventions are distinct, each from the other because of the following reasons:

A) Groups I, II, and IV-VII are drawn to methods comprising different steps and parameters, such as the step in Group I relating to lack of denaturing conditions; the step in Group II relating to use of a terminal deoxynucleotidyl transferase; the step in Group IV relating to use as a hybridization probe; the step in Group V relating to reverse-transcribing messenger RNA; the step in Group VI relating to partially degrading RNA in a sample; and the step in VII relating to hybridization of nucleic acids from a first and second sample for comparative genome hybridization. Thus, each of these methods is distinct and unobvious over the others.

B) The microarray of Group III is not used in any of the methods of Groups I, II, or IV-VII.

C) The microarray of Group III is not related in any way to the kits of Group VIII.

D) Inventions VIII and (I, II, and IV-VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kits of Group VIII can be used in any of the materially different methods of Groups I, II, and IV-VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, or because the full search required for any of Groups (I, V, VI, and VIII) and (IV, VII) is not required for any other Group having the same classification, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Robert Hodges on 08/19/04 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-161 and 214-287. Affirmation of this election must be made by applicant in replying to this Office action. Claims 162-213 and 288-296 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The specification is objected to because of the following informalities: apparently inappropriate text appears in the specification on page 47, line 28; page 35, line 15; page 23, line 3. Correction is required.

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed (i.e., multiple displacement amplification).

6. Claims 27, 36, and 111-136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 27 and 36 are confusing because it cannot be determined what is encompassed by "substantially isothermic" and "substantial complexity" in claims 27 and 36, respectively. Clarification is required.

B) Claims 111-136 are confusing because it cannot be determined what is encompassed by a "target sample", especially one in which nucleic acids "are not separated from other material in the target sample". Such language implies that "other material" is present in said target sample, but what is contemplated by this "other material" is unclear.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 111, 138, and 139 are rejected under 35 U.S.C. 102(b) as being anticipated by Lizardi (US 6,124,120).

Claim 111 is drawn to a method of multiple displacement amplification using a target sample, wherein nucleic acids in the target sample are not separated from other material in the target sample. Claims 138 and 139 are drawn to a method of multiple displacement amplification, using primers which are 5-10 nucleotides long, which may have random sequences.

Lizardi discloses the basic method of multiple displacement amplification (see entire patent). With respect to claim 111, Lizardi discloses in Example 1 in columns 24-26 the use of a nucleic acid sample in multiple displacement amplification, wherein said sample comprises lambda DNA as well as "other material" – specifically, T4 DNA ligase and T4 DNA ligase buffer. The lambda DNA is not separated from these other materials before amplification.

With respect to claims 138 and 139, Lizardi discloses primers of generally 10-35 nucleotides long (column 6, lines 22-23), and primers having random or partially random sequences (column 8, lines 60-63).

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 161 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,617,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims are generic to the patented species claims. In other words, the "target nucleic acid sequences" of the pending claims are a genus containing the "whole genome" or "chromosome" of the patented claims.

9. Claims 1-110, 112-137, 140-161, and 214-287 are free of the prior art, although 1-10, 27, 36, and 111-136 are rejected for other reasons. These claims represent patentable variations of the multiple displacement amplification method of Lizardi. No prior art has been found teaching or suggesting modifying the method of Lizardi by: not subjecting the target nucleic acid sample to denaturing conditions (claims 1-110, 144, 147-161); using a crude or impure biological sample to provide target nucleic acid

(claims 112-137); using primers 5-8 nucleotides long (claims 140-142); using nuclease resistant primers having modified bases (claim 143); adding an additional dilution step followed by another round of amplification (claims 145-146); using a circular nucleic acid molecule comprising the target sequence (claim 214); and using a cell lysate in the amplification reaction (claims 224-287).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kenneth R. Horlick, Ph.D.

Kenneth R Horlick
Primary Examiner
Art Unit 1637

08/30/04